

ACT NO. 368, PUBLIC ACTS OF 1978
PART 135. RADIATION CONTROL

333.13501. Definitions; principles of construction.

Sec. 13501. (1) As used in this part:

- (a) "General license" means a license, effective pursuant to rules promulgated by the department without the filing of an application, to transfer, acquire, own, possess, or use quantities of, or devices or equipment utilizing, radioactive material.
- (b) "Ionizing radiation" means gamma rays and x-rays, alpha particles, beta particles, high speed electrons, neutrons, protons, high speed ions, and other high speed nuclear particles.
- (c) "Mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.
- (d) "Mammography authorization" means authorization under section 13523 to use a radiation machine for mammography.
- (e) "Mammography interpreter" means an individual who meets the requirements set forth in section 13523(2)(g) and is responsible for evaluating and interpreting mammographic images.
- (f) "Person" means a person as defined in section 1106 or a governmental entity.
- (g) "Radioactive material" means a solid, liquid, or gas material which emits ionizing radiation spontaneously.
- (h) "Radiography" means the making of a film or other record of an internal structure of the body by passing x-rays or gamma rays through the body to act on film or other image receptor.
- (i) "Registration" means registration of a source of ionizing radiation in writing with the department.
- (j) "Source of ionizing radiation" means a device or material that emits ionizing radiation.
- (k) "Specific license" means a license issued to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of, or devices or equipment utilizing, radioactive material.

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code.

333.13505. License, registration, or exemption required.

Sec. 13505. A person shall not manufacture, produce, transport, transfer, dispose of, acquire, own, possess, or use a radioactive material or other source of ionizing radiation unless licensed, registered, or exempted by the department in accordance with rules promulgated pursuant to this part or unless exempted by this part.

333.13506. Applicability of §§ 333.13505 and 333.13515 to 333.13536.

Sec. 13506. Sections 13505 and 13515 to 13536 do not apply to the following sources or conditions, except as noted:

- (a) Electrical or other equipment or material not intended primarily to produce radiation which, by nature of design, does not produce radiation at the point of nearest approach at a weekly rate higher than 1/10 the appropriate limit generally accepted by the medical profession and for any critical organ exposed. The production testing or production servicing of the equipment is not exempt.
- (b) A radiation machine during process of manufacture or in storage or transit. The production testing or production servicing of the machine is not exempt.
- (c) A radioactive material while being transported under the jurisdiction of and in conformity with regulations adopted by the nuclear regulatory commission or the United States department of transportation, or their successors, specifically applicable to the transportation of such radioactive material.
- (d) Sound waves, radio waves, and visible, infrared, or ultraviolet light.
- (e) A production or utilization facility, as defined in the federal atomic energy act of 1954, 42 U.S.C. 2011 to 2281, or a source of ionizing radiation used in or in connection with the operation of a production or utilization facility pursuant to a license from the federal nuclear regulatory commission or successor thereto. However, the department may collect radiation data and perform environmental monitoring in connection with the operation of the facility in accordance with this part.
- (f) A source material, by-product material, or special nuclear material over which the federal nuclear regulatory commission or a successor thereto has exclusive regulatory jurisdiction under the federal atomic energy act of 1954, which jurisdiction has not been transferred to this state pursuant to an agreement under Act No. 54 of the Public Acts of 1965, being sections 3.801 and 3.802 of the Michigan Compiled Laws.

333.13511. Agreements as to inspections, environmental monitoring, or other functions.

Sec. 13511. (1) The governor may enter into agreements with the federal government, other states, or interstate agencies, whereby the department shall perform for or on a cooperative basis with the federal government, other states, or interstate agencies inspections, environmental monitoring, or other functions relating to control of sources of ionizing radiation.

(2) An agreement entered into pursuant to subsection (1) does not transfer, delegate, or impose upon the department any

power, authority, or responsibility that is not fully consistent with this part.

333.13515. Department as radiation control agency; duties generally.

Sec. 13515. (1) The department is designated as the radiation control agency of this state and shall coordinate radiation control programs of state departments acting within their statutory authorities.

(2) Pursuant to rules promulgated under this part, the department shall require licensing and registration of radioactive materials and other sources of ionizing radiation.

(3) The department shall develop and conduct programs for evaluation and control of hazards associated with the use of radioactive materials and other sources of ionizing radiation.

333.13516. Finding of emergency; emergency order; hearing; continuing, modifying, or revoking order.

Sec. 13516. When the department finds that an emergency exists requiring immediate action to protect occupational or public health and safety, the department shall issue an order, with or without notice or hearing, reciting the existence of the emergency and providing for the protection of public health and safety. Notwithstanding this act or the administrative procedures act of 1969, the order shall be effective immediately.

A person to whom the order is directed shall comply therewith immediately but on request to the department shall be granted a hearing within 15 days. On the basis of the hearing, the emergency order shall be continued, modified, or revoked within 30 days after the hearing.

333.13517. Right of entry to determine compliance or violation; warrant; search and seizure.

Sec. 13517. (1) The department may enter at all reasonable times upon private or public property upon which sources of ionizing radiation are reasonably believed to be located, with the permission of the owner or custodian thereof, to determine if there is compliance with or violation of this part or a rule or license.

(2) If the department has reasonable or probable cause to believe that a violation of this part or a rule or license is being committed on private or public property or that there exists on the property evidence of a violation, and permission to enter thereon is denied by the owner or custodian thereof, the department may apply to the proper judicial officer under Act No. 189 of the Public Acts of 1966, being sections 780.651 to 780.659 of the Michigan Compiled Laws, for a warrant commanding the sheriff or a law enforcement officer, with the aid of the department, to search the property and seize any source of ionizing radiation that is possessed, controlled, or used wholly or partially in violation of this part or a rule or license, or any evidence of a violation of this part or a rule or license.

333.13518. Operation of environmental monitoring systems; collection and coordination of radiation data.

Sec. 13518. The department shall operate and collect data from environmental monitoring systems in the environs of facilities which emit or could emit significant quantities of radioactive material effluents to measure the effect on public health and safety. The department shall receive and coordinate radiation data collected by other state departments.

333.13521. Rules generally.

Sec. 13521. (1) The department shall promulgate rules providing for general or specific licenses or registration, or exemption from licensing or registration, for radioactive materials and other sources of ionizing radiation. The rules shall provide for amendment, suspension, or revocation of licenses. In connection with those rules, the department may promulgate rules to establish requirements for record keeping, permissible levels of exposure, notification and reports of accidents, protective measures, technical qualifications of personnel, handling, transportation, storage, waste disposal, posting and labeling of hazardous sources and areas, surveys, and monitoring.

(2) The rules shall not limit the intentional exposure of patients to radiation for the purpose of lawful therapy or research conducted by licensed health professionals.

(3) The department shall promulgate rules specifying the minimum training and performance standards for an individual using a radiation machine for mammography as set forth in section 13523.

333.13522. Rules; avoiding dual licensing; recognition of other state or federal licenses; schedule of fees; deposit of fees; nonrefundable fees in connection with mammography authorization; waiver of fee; waiver prohibited; adjustment of fees.

Sec. 13522. (1) In promulgating rules pursuant to this part, the department shall avoid requiring dual licensing, insofar as practical. Rules promulgated by the department may provide for recognition of other state or federal licenses as the department considers desirable, subject to registration requirements prescribed by the department. A person who, on the effective date of an agreement under Act No. 54 of the Public Acts of 1965, being sections 3.801 to 3.802 of the Michigan Compiled Laws, possesses a license issued by the federal government for a source of ionizing radiation of the type for which the state assumes regulatory responsibility under the agreement, is considered to possess an identical license issued pursuant to this part, which license expires either 90 days after receipt of a written notice of termination from the department or on the date of expiration stated in the federal license, whichever occurs first.

(2) The department may promulgate rules to establish a schedule of fees to be paid by applicants for licenses for radioactive materials and devices and equipment utilizing the radioactive materials.

(3) Except as otherwise provided in this subsection, the department may promulgate rules to establish a schedule of fees to be paid by an applicant for a license for other sources of ionizing radiation and the renewal of the license, and by a person possessing sources of ionizing radiation that are subject to registration. The registration or registration renewal fee for a radiation machine registered under this part is \$45.00 for the first veterinary or dental x-ray or electron tube and \$25.00 for each additional veterinary or dental x-ray or electron tube annually, or \$75.00 annually per nonveterinary or nondental x-ray or electron tube. The department shall not assess a fee for the amendment of a radiation machine registration certificate. In addition, the department shall assess a fee of \$100.00 for each follow-up inspection due to noncompliance during the same year. The department may accept a written certification from the licensee or registrant that the items of noncompliance have been corrected instead of performing a follow-up inspection. If the department does not inspect a source of ionizing radiation for a period of 5 consecutive years, the licensee or registrant of the source of ionizing radiation does not have to pay further license or registration fees as to that source of ionizing radiation until the first license or registration renewal date following the time an inspection of the source of ionizing radiation is made.

(4) A fee collected under this part shall be deposited in the state treasury and credited to the general fund of this state.

(5) Except as otherwise provided in subsection (6), the department shall assess the following nonrefundable fees in connection with mammography authorization:

- (a) Inspection, per radiation machine\$100.00
 - (b) Reinspection for reinstatement of mammography authorization, per radiation machine\$100.00
 - (c) Department evaluation of compliance with section 13523(2)(a), per radiation machine\$700.00
- Each reevaluation of a radiation machine due to failure during the previous evaluation, relocation of the radiation machine, or similar changes that could affect earlier evaluation results\$300.00

(6) If an applicant for mammography authorization submits an evaluation report issued by the American college of radiology that evidences compliance with section 13523(2)(a), the department shall waive the fee under subsection (5) for department evaluation of compliance with that provision.

(7) Except as otherwise provided in subsections (3) and (6), the department shall not waive a fee required under this section.

(8) The department shall adjust on an annual basis the fees prescribed by subsections (3) and (5) by an amount determined by the state treasurer to reflect the cumulative annual percentage change in the Detroit consumer price index, not to exceed 5%. As used in this subsection, "Detroit consumer price index" means the most comprehensive index of consumer prices available for the Detroit area from the bureau of labor statistics

of the United States department of labor.

333.13523. Radiation machine; registration; temporary authorization; authorization; standards; application; certificate; inspections; denial or withdrawal of authorization; hearing; emergency order; reinstatement of authorization; fine; notice; rules; definitions.

Sec. 13523. (1) Beginning August 16, 1989, a person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department under department rules for registration of radiation machines and is specifically authorized under this section for use for mammography.

(2) The department shall authorize a radiation machine for use for mammography if the radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet all of the following standards:

- (a) The radiation machine and the facility in which the radiation machine is used meet the criteria for the American college of radiology mammography accreditation program dated August, 1993 and published by the American college of radiology in the documents entitled "overview, mammography accreditation program, and ACR standards for the performance of screening mammography," which documents and criteria are incorporated by reference, excluding the physician interpreter and the accreditation fee schedule. The department shall make copies of those criteria available to the public and may by rule adopt modified criteria. The department may accept an evaluation report issued by the American college of radiology as evidence that a radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet those criteria. If at any time the department determines that it will not accept any evaluation reports issued by the American college of radiology as evidence that a radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet those criteria, the department shall promptly notify each person who has registered a radiation machine used exclusively to perform mammography under this part and the rules promulgated under this part.
- (b) The radiation machine, the film or other image receptor used in the radiation machine, and the facility in which the radiation machine is used meet the requirements set forth in department rules for radiation machines.
- (c) The radiation machine is specifically designed to perform mammography.
- (d) The facility in which the radiation machine is used does all of the following:
 - (i) At least annually has a qualified radiation physicist provide on-site consultation to the facility, including, but not limited to, a complete evaluation of the entire mammography system to

- ensure compliance with this part and the rules promulgated under this part.
- (ii) Maintains for at least 7 years records of the consultation required in subparagraph (i) and the findings of the consultation.
 - (iii) Designates a physician or osteopathic physician licensed under article 15 to provide medical direction for the delivery of mammography services and to be responsible for the clinical aspects of the x-ray examinations and other procedures related to mammography. The physician designated under this subparagraph is responsible for conducting an on-site visit to each mammography station within the facility at least monthly for the purpose of providing professional feedback regarding clinical image quality and quality assurance procedures, for review of quality control documentation, and for ensuring that safe operating procedures are used in the delivery of mammographic services. If the physician designated under this subparagraph practices primarily outside of the facility, the physician shall keep a log of each on-site visit signed by the physician. The chief administrative officer of the facility or his or her designee may request to view the log at any time. The physician designated under this subparagraph shall meet the requirements of subdivision (g)(i) and (ii) or, until January 1, 1996, the requirements of subdivision (g)(ii) and (iii).
 - (e) The radiation machine is used according to department rules on patient radiation exposure and radiation dose levels.
 - (f) Each individual who operates the radiation machine can demonstrate to the department that he or she is specifically trained in mammography or an individual who is a physician or an osteopathic physician, and beginning 60 days after the rules required under section 13521(3) are promulgated, each individual who operates the radiation machine can demonstrate to the department that he or she meets the standards required by those rules or an individual who is a physician or an osteopathic physician.
 - (g) The x-ray images of each mammographic examination performed with the radiation machine are interpreted by a mammography interpreter who is a physician or osteopathic physician licensed under article 15 and who meets the requirements of subparagraphs (i), (ii), (iii), (iv), and (v):
 - (i) except as otherwise provided in this subparagraph, is certified in radiology or diagnostic radiology by the American board of radiology or the American osteopathic board of radiology, has been eligible for certification in radiology or diagnostic radiology for not more than 2 years, or is certified or determined to be qualified in radiology or diagnostic radiology by another professional organization approved by the radiation advisory board appointed under section 13531. Until the expiration of 2 years after the effective date of the amendatory act that added this subdivision, a physician or osteopathic physician licensed under article 15 who has been eligible for certification in radiology or diagnostic radiology for more than 2 years shall be considered to meet the requirement of this subparagraph.
 - (ii) Shall successfully complete or teach not less than 15 hours of continuing medical education every 3 years after the effective date of the amendatory act that added this subdivision in the technical aspects or clinical aspects, or both, of mammography in courses or programs approved by the individual's respective specialty organization and licensing board and has documentation of successful completion of the training that is satisfactory to the department.
 - (iii) Shall have successfully completed not less than 2 months of formal training in reading mammograms with instruction in medical radiation physics, radiation effects, and radiation protection and has documentation of successful completion of the training that is satisfactory to the department. For purposes of this subparagraph, the department may accept time spent in a residency program that includes specific training in mammography if the individual has documentation of the residency program that is satisfactory to the department.
 - (iv) Interprets not less than 520 mammographic examinations each year.
 - (v) Maintains annual records concerning outcome data for correlation of positive mammograms to biopsies done, and the number of cancers detected.
- (3) The department may issue a nonrenewable temporary authorization for a radiation machine for use for mammography if additional time is needed to allow submission of evidence satisfactory to the department that the radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet the standards set forth in subsection (2) for approval for mammography. A temporary authorization granted under this subsection after February 16, 1991 is effective for no more than 12 months. The department may withdraw a temporary authorization before its expiration if the radiation machine, the personnel operating the radiation machine, or the facility in which the machine is used does not meet 1 or more of the standards set forth in subsection (2).
- (4) To obtain authorization from the department to use a radiation machine for mammography, the person who owns or leases the radiation machine or an authorized agent of the person shall apply to the department for mammography authorization on an application form provided by the department and shall provide all of the information required by the department as specified on the application form. A person who

owns or leases more than 1 radiation machine used for mammography shall obtain authorization for each radiation machine. The department shall process and respond to an application within 30 days after the date of receipt of the application. Upon determining to grant mammography authorization for a radiation machine, the department shall issue a certificate of registration specifying mammography authorization for each authorized radiation machine. A mammography authorization is effective for 3 years contingent upon the radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is operated for which the mammography authorization is issued meeting 1 of the following requirements:

- (a) Maintaining continued accreditation by the American college of radiology.
- (b) Having an active accreditation application in process with the American college of radiology.
- (c) Maintaining approval or being in the process of obtaining approval under a department evaluation process equivalent to that described in subdivisions (a) and (b).

(5) No later than 60 days after initial mammography authorization of a radiation machine under this section, the department shall inspect the radiation machine. After that initial inspection, the department shall annually inspect the radiation machine and may inspect the radiation machines more frequently. The department shall make reasonable efforts to coordinate the inspections under this section with the department's other inspections of the facility in which the radiation machine is located.

(6) After each satisfactory inspection by the department, the department shall issue a certificate of radiation machine inspection or a similar document identifying the facility and radiation machine inspected and providing a record of the date the radiation machine was inspected. The facility shall post the certificate or other document near the inspected radiation machine.

(7) The department may withdraw the mammography authorization for a radiation machine if it does not meet 1 or more of the standards set forth in subsection (2).

(8) The department shall provide an opportunity for a hearing in connection with a denial or withdrawal of mammography authorization.

(9) Upon a finding that a deficiency in a radiation machine used for mammography or a violation of this part or the rules promulgated under this part seriously affects the health, safety, and welfare of individuals upon whom the radiation machine is used for mammography, the department may issue an emergency order summarily withdrawing the mammography authorization of the radiation machine. The department shall incorporate its findings in the order and shall provide an opportunity for a hearing within 5 working days after issuance of the order. The order is effective during the proceedings.

(10) If the department withdraws the mammography

authorization of a radiation machine, the radiation machine shall not be used for mammography. An application for reinstatement of a mammography authorization shall be filed and processed in the same manner as an application for mammography authorization under subsection (4), except that the department shall not issue a reinstated certificate of mammography registration until the department receives the reinspection fee required under section 13522(5), inspects the radiation machine, and determines that it meets the standards set forth in subsection (2). The department shall conduct an inspection required under this subsection no later than 60 days after receiving a proper application for reinstatement of a mammography authorization.

(11) In addition to the penalties provided in section 13535 and the reinspection fee required under section 13522(5), if a person violates subsection (1), the department may impose an administrative fine against the owner of the radiation machine or, if a lessee of the radiation machine has effective control of the radiation machine, the lessee, of not more than \$500.00 for each calendar week in which a mammography is performed in violation of subsection (1). If a person continues to violate subsection (1) for a period of 2 weeks after a fine is imposed under this subsection, the department shall post a conspicuous notice on the unauthorized radiation machine and at the entry to the facility where the radiation machine is located warning the public that the facility is performing mammography using a radiation machine that is a substantial hazard to the public health.

(12) The department may promulgate rules necessary to implement this section after consultation with the radiation advisory board established under section 13531.

(13) As used in this section:

- (a) "Radiation machine" means a machine, other than those exempted by department rule, that emits ionizing radiation.
- (b) "Mammography system" means the radiation machine used for mammography; automatic exposure control devices; films, screens, and cassettes; image processor; darkroom; and viewboxes.

333.13525. Licensing, regulation, or registration by municipalities prohibited.

Sec. 13525. A municipality or a department, agency, or official of a municipality may not license, regulate, or require the registration of a radioactive material or other source of ionizing radiation.

333.13531. Radiation advisory board; appointment, qualifications, and terms of members; expenses; duty to furnish technical advice.

Sec. 13531. The governor shall appoint, with the advice and consent of the senate, a radiation advisory board of 9 members, 3 of whom shall represent industry, 3 the healing arts, and 3 the public and private institutions of higher learning.

Members of the board shall serve at the pleasure of the governor. The members shall be reimbursed for necessary and actual expenses incurred in attendance at meetings or for authorized business of the board pursuant to section 1216. The board shall furnish to the department technical advice the board deems desirable or the department may reasonably request on matters relating to the radiation control program.

333.13535. Violations; penalties.

Sec. 13535. A person who violates this part or a rule promulgated under this part or who fails to obtain or comply with conditions of licensure or registration under this part is guilty of a misdemeanor, punishable by imprisonment for not more than 180 days, or a fine of not more than \$10,000.00, or both. A court may fine a person not more than \$2,000.00 for each violation of this part. Each day a violation continues shall be a separate violation.

333.13536. Injunction; order directing compliance.

Sec. 13536. If, after thorough investigation by the department, it is the judgment of the department that a person has engaged in or is about to engage in an act or practice which constitutes a violation of this part or a rule or order, the attorney general, at the request of the department, shall make application to the appropriate circuit court for an order enjoining the act or practice or for an order directing compliance with this part or a rule or order issued pursuant to this part.